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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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Pendorf & Cutiff
511 Memorial HWY.
Tampa, FL 33634-7356

EXAMINER

KOSSON, ROSANNE

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1653

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,723

Applicant(s)

KRAMER ET AL.

Examiner

Rosanne Kosson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 and 8, drawn to the isolated polypeptide of SEQ ID NO: 3 or an allele (sic) or derivative thereof.

Group II, claim(s) 1, 9 and 10, drawn to the isolated polypeptide of SEQ ID NO: 4 or an allele (sic) or derivative thereof.

Group III, claim(s) 1, 9 and 10, drawn to the isolated polypeptide of SEQ ID NO: 6 or an allele (sic) or derivative thereof.

Group IV, claim(s) 1 and 8, drawn to the isolated polypeptide of SEQ ID NO: 7 or an allele (sic) or derivative thereof.

Group V, claim(s) 2-6, 11-15, and 23, drawn to the isolated polynucleotide of SEQ ID NO: 1 or a vector or host cell comprising the polynucleotide.

Group VI, claim(s) 2-5, 7 and 11-15, drawn to the isolated polynucleotide of SEQ ID NO: 2 or a vector or host cell comprising the polynucleotide.

Group VI, claim(s) 2-5, 7 and 11-15, drawn to the isolated polynucleotide of SEQ ID NO: 5 or a vector or host cell comprising the polynucleotide.

Group VIII, claim(s) 2-6, 11-15, and 23, drawn to the isolated polynucleotide of SEQ ID NO: 7 or a vector or host cell comprising the polynucleotide.

Group IX, claim(s) 16 and 24, drawn to the use of the polynucleotide of SEQ ID NO: 1 for making transgenic mammals.

Group X, claim(s) 16 and 24, drawn to the use of the polynucleotide of SEQ ID NO: 2 for making transgenic mammals.

Group XI, claim(s) 16 and 24, drawn to the use of the polynucleotide of SEQ ID NO: 5 for making transgenic mammals.

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Group XII, claim(s) 16 and 24, drawn to the use of the polynucleotide of SEQ ID NO: 7 for making transgenic mammals.

Group XIII, claim(s) 17 and 25, drawn to the use of the polypeptide of SEQ ID NO: 3 for making an antibody to it.

Group XIV, claim(s) 17, drawn to the use of the polypeptide of SEQ ID NO: 4 for making an antibody to it.

Group XV, claim(s) 17, drawn to the use of the polypeptide of SEQ ID NO: 6 for making an antibody to it.

Group XVI, claim(s) 17 and 25, drawn to the use of the polypeptide of SEQ ID NO: 8 for making an antibody to it.

Group XVII, claim(s) 18 and 26, drawn to the use of an antibody to the polypeptide of SEQ ID NO: 3 in a diagnostic method.

Group XVIII, claim(s) 18 and 26, drawn to the use of an antibody to the polypeptide of SEQ ID NO: 3 in a therapeutic treatment method.

Group XIX, claim(s) 18 and 26, drawn to the use of an antibody to the polypeptide of SEQ ID NO: 3 in a cosmetic treatment method.

Group XX, claim(s) 18, drawn to the use of an antibody to the polypeptide of SEQ ID NO: 4 in a diagnostic method.

Group XXI, claim(s) 18, drawn to the use of an antibody to the polypeptide of SEQ ID NO: 4 in a therapeutic treatment method.

Group XXII, claim(s) 18, drawn to the use of an antibody to the polypeptide of SEQ ID NO: 4 in a cosmetic treatment method.

Group XXIII, claim(s) 18, drawn to the use of an antibody to the polypeptide of SEQ ID NO: 6 in a diagnostic method.

Group XXIV, claim(s) 18, drawn to the use of an antibody to the polypeptide of SEQ ID NO: 6 in a therapeutic treatment method.

Group XXV, claim(s) 18, drawn to the use of an antibody to the polypeptide of SEQ ID NO: 6 in a cosmetic treatment method.

Group XXVI, claim(s) 18 and 26, drawn to the use of an antibody to the polypeptide of SEQ ID NO: 8 in a diagnostic method.

Group XXVII, claim(s) 18 and 26, drawn to the use of an antibody to the polypeptide of SEQ ID NO: 8 in a therapeutic treatment method.

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Group XXVIII, claim(s) 18 and 26, drawn to the use of an antibody to the polypeptide of SEQ ID NO: 8 in a cosmetic treatment method.

Group XXIX, claim(s) 19 and 27, drawn to an antibody to the polypeptide of SEQ ID NO: 3.

Group XXX, claim(s) 19, drawn to an antibody to the polypeptide of SEQ ID NO: 4.

Group XXXI, claim(s) 19, drawn to an antibody to the polypeptide of SEQ ID NO: 6.

Group XXXII, claim(s) 19 and 27, drawn to an antibody to the polypeptide of SEQ ID NO: 8.

Group XXXIII, claim(s) 20, 28 and 32, drawn to a reagent for detecting a keratinocyte protein that is manufactured with the polynucleotide of SEQ ID NO: 1.

Group XXXIV, claim(s) 20, 28 and 32, drawn to a reagent for detecting a keratinocyte protein that is manufactured with the polynucleotide of SEQ ID NO: 2.

Group XXXV, claim(s) 20, 28 and 32, drawn to a reagent for detecting a keratinocyte protein that is manufactured with the polynucleotide of SEQ ID NO: 5.

Group XXXVI, claim(s) 20, 28 and 32, drawn to a reagent for detecting a keratinocyte protein that is manufactured with the polynucleotide of SEQ ID NO: 7.

Group XXXVII, claim(s) 21, drawn to the use of the polynucleotide of SEQ ID NO: 1 in a diagnostic method.

Group XXXVIII, claim(s) 21, drawn to the use of the polynucleotide of SEQ ID NO: 1 in a therapeutic treatment method.

Group XXXIX, claim(s) 21, drawn to the use of the polynucleotide of SEQ ID NO: 1 in a cosmetic treatment method.

Group XXXX, claim(s) 21, drawn to the use of the polynucleotide of SEQ ID NO: 2 in a diagnostic method.

Group XXXXI, claim(s) 21, drawn to the use of the polynucleotide of SEQ ID NO: 2 in a therapeutic treatment method.

Group XXXXII, claim(s) 21, drawn to the use of the polynucleotide of SEQ ID NO: 2 in a cosmetic treatment method.

Group XXXXIII, claim(s) 21, drawn to the use of the polynucleotide of SEQ ID NO: 5 in a diagnostic method.

Group XXXXIV, claim(s) 21, drawn to the use of the polynucleotide of SEQ ID NO: 5 in a therapeutic treatment method.

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Group XXXXV, claim(s) 21, drawn to the use of the polynucleotide of SEQ ID NO: 5 in a cosmetic treatment method.

Group XXXXVI, claim(s) 21, drawn to the use of the polynucleotide of SEQ ID NO: 7 in a diagnostic method.

Group XXXXVII, claim(s) 21, drawn to the use of the polynucleotide of SEQ ID NO: 7 in a therapeutic treatment method.

Group XXXXVIII, claim(s) 21, drawn to the use of the polynucleotide of SEQ ID NO: 7 in a cosmetic treatment method.

Group XXXXIX, claim(s) 22, drawn to the use of the polypeptide of SEQ ID NO: 3 in a diagnostic method.

Group L, claim(s) 22, drawn to the use of the polypeptide of SEQ ID NO: 3 in a therapeutic treatment method.

Group LI, claim(s) 22, drawn to the use of the polypeptide of SEQ ID NO: 3 in a cosmetic treatment method.

Group LII, claim(s) 22, drawn to the use of the polypeptide of SEQ ID NO: 4 in a diagnostic method.

Group LIII, claim(s) 22, drawn to the use of the polypeptide of SEQ ID NO: 4 in a therapeutic treatment method.

Group LIV, claim(s) 22, drawn to the use of the polypeptide of SEQ ID NO: 4 in a cosmetic treatment method.

Group LV, claim(s) 22, drawn to the use of the polypeptide of SEQ ID NO: 6 in a diagnostic method.

Group LVI, claim(s) 22, drawn to the use of the polypeptide of SEQ ID NO: 6 in a therapeutic treatment method.

Group LVII, claim(s) 22, drawn to the use of the polypeptide of SEQ ID NO: 6 in a cosmetic treatment method.

Group LVIII, claim(s) 29, drawn to the use of an oligonucleotide from SEQ ID NO: 1 in a diagnostic method.

Group LIX, claim(s) 29, drawn to the use of an oligonucleotide from SEQ ID NO: 1 in a therapeutic treatment method.

Group LX, claim(s) 29, drawn to the use of an oligonucleotide from SEQ ID NO: 1 in a cosmetic treatment method.

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Group LXI, claim(s) 29, drawn to the use of an oligonucleotide from SEQ ID NO: 7 in a diagnostic method.

Group LXI, claim(s) 29, drawn to the use of an oligonucleotide from SEQ ID NO: 7 in a therapeutic treatment method.

Group LXIII, claim(s) 29, drawn to the use of an oligonucleotide from SEQ ID NO: 7 in a cosmetic treatment method.

Group LXIV, claim(s) 30, 31 and 35, drawn to a reagent for detecting a keratinocyte protein that is manufactured with the polypeptide of SEQ ID NO: 3.

Group LXV, claim(s) 30, drawn to a reagent for detecting a keratinocyte protein that is manufactured with the polypeptide of SEQ ID NO: 4.

Group LXVI, claim(s) 30, drawn to a reagent for detecting a keratinocyte protein that is manufactured with the polypeptide of SEQ ID NO: 6.

Group LXVII, claim(s) 30, 31 and 35, drawn to a reagent for detecting a keratinocyte protein that is manufactured with the polypeptide of SEQ ID NO: 8.

Group LXVIII, claim(s) 33, drawn to the use of the polypeptide of SEQ ID NO: 3 for identifying binding partners that affect the function or expression of the polypeptide.

Group LXIX, claim(s) 33, drawn to the use of the polypeptide of SEQ ID NO: 8 for identifying binding partners that affect the function or expression of the polypeptide.

Group LXX, claim(s) 34, drawn to the use of the polynucleotide of SEQ ID NO: 1 for identifying binding partners that affect the function or expression of the polynucleotide.

Group LXXI, claim(s) 34, drawn to the use of the polynucleotide of SEQ ID NO: 2 for identifying binding partners that affect the function or expression of the polynucleotide.

Group LXXII, claim(s) 34, drawn to the use of the polynucleotide of SEQ ID NO: 5 for identifying binding partners that affect the function or expression of the polynucleotide.

Group LXXIII, claim(s) 34, drawn to the use of the polynucleotide of SEQ ID NO: 7 for identifying binding partners that affect the function or expression of the polynucleotide.

The inventions are distinct, each from the other because of the following reasons:

The inventions listed as Groups I – LXXIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The requirement of unity of invention is not fulfilled because there is no technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" means those technical features that define

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a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. There is no corresponding special technical feature because there is no corresponding technical feature shared by all the groups. Each sequence, whether protein or DNA is a separate and distinct sequence, and only one sequence will be searched in each application. Because each sequence is a separate invention, methods of using different sequences are also different inventions.

Also, the specification makes it abundantly clear that each polypeptide is different from the other polypeptides and each polynucleotide is different from the other polynucleotides. Therefore, claims relating to the polypeptides do not share the same special technical feature, nor do claims relating to the polynucleotides. Claim 2 claims nucleotide sequences that hybridize under any conditions to any part of the claimed full-length sequences. This reads on the trinucleotide CAT which hybridizes to ATG, which is present in any nucleic acid sequence encoding a protein, such as the claimed sequences. CAT encodes the amino acid tyrosine. Because part of the claimed subject matter, CAT, is known in the art, the technical feature does not represent an advance over the prior art and, therefore, each invention lacks unity with any of the others.

As indicated above, Applicants must choose **ONE** polypeptide or polynucleotide sequence from among those claimed, that is, one of SEQ ID NOS: 1-8. Each sequence is a distinct invention requiring separate searches. These are **NOT** species. Each sequence is a chemically, structurally and functionally distinct molecule. Therefore, the each of these sequences is patentably distinct. Moreover, each sequence requires a separate set of searches. Applicants should note that searching each sequence imposes a serious search burden. Currently, there are approximately eight different databases that accompany the results of a search for one discrete amino acid or polynucleotide sequence, and each result set from a particular database must be carefully considered. Each set of prior art has its own considerations with respect to anticipation and obviousness. Hence, the search for even two different sequences in the databases, in addition to searching the organic molecule databases, would require extensive searching and review. Therefore, these inventions are patentably distinct.

Accordingly, a holding of lack of unity of invention is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn

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process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

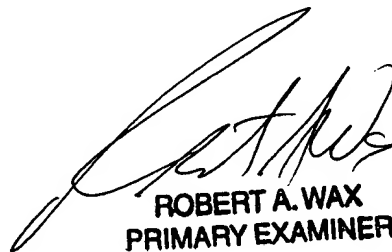
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner, Art Unit 1653

rk/2006-03-08

Rosanne Kosson


ROBERT A. WAX
PRIMARY EXAMINER